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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/687,993	10/13/2000	Shaw-Fen Sylvia Hu	A-357C	2749

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US Patent Operations DRC  
Dept. 4300/MS 27-4-A  
AMGEN INC.  
One Amgen Center Drive  
Thousand Oaks, CA 91320-1799

EXAMINER

GUCKER, STEPHEN

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 09/19/2002

4

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/687,993

Applicant(s)

HU, SHAW-FEN SYLVIA

Examiner

Gudker

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 10.April.2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 31,32 and 45-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 31-32 and 45-49 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claim 31 and 45-49 (each in part) drawn to a method for affecting the survival or function of neurons comprising administering a polynucleotide encoding a truncated glial cell line-derived neurotrophic factor (GDNF) protein product, classified in class 514, subclass 44, for example.
  - II. Claim 32 and 45-49 (each in part) drawn to a method comprising implanting in a patient a cell transformed with a polynucleotide to provide *in vivo* production of a truncated GDNF protein, classified in class 424, subclass 520, for example.
2. The inventions are distinct, each from the other because of the following reasons:
3. Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive Inventions that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions I and II are directed to methods that are distinct both physically and functionally, and are not required one for the other. Invention I requires search and consideration of administering a polynucleotide for affecting the survival or function of neurons, which is not required by Invention II. Invention II requires search and consideration of implanting in a patient a cell transformed with a polynucleotide, which is not required by Invention I.

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4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, separate search requirements, and/or different classification, restriction for examination purposes as indicated is proper.

**5. FURTHERMORE, restriction to one of the following inventions is required under 35 U.S.C. 121:**

- a. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 3.
- b. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 4.
- c. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 5.
- d. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 6.
- e. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 7.
- f. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 8.
- g. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 9.
- h. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 10.
- i. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 11.
- j. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 12.
- k. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 13.
- l. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 14.
- m. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 15.
- n. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 16.
- o. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 17.

- p. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 18.
- q. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 19.
- r. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 20.
- s. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 21.
- t. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 22.
- u. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 23.
- v. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 24.
- w. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 25.
- x. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 26.
- y. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 27.
- z. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 28.
- aa. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 29.
- bb. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 30.
- cc. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 31.
- dd. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 32.
- ee. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 33.
- ff. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 34.
- gg. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 35.
- hh. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 36.
- ii. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 37.
- jj. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 38.
- kk. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 42.

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- ll. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 44.
  - mm. Claims 31-32 and 45-49, each in part, as the inventions pertain to SEQ ID NO: 46.
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- 6. The inventions are distinct, each from the other because of the following reasons:
  - 7. Each sequence requires a separate search of the literature and sequence databases. A search and examination of an Invention as it pertains for all 39 sequences would therefore present the examiner with an undue search burden.
  - 8. Applicant is advised that the restriction requirement between SEQ ID NOS: 3-38, 42, 44, and 46 is not a requirement for election of species. Rather, it is a second layer of restriction requirement between independent and distinct Inventions. In order to be fully responsive, Applicant must elect one from I-II and one from (a)-(mm).
  - 9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter and separate search requirements, restriction for examination purposes as indicated is proper.
  - 10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday through Friday, 8:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, Ph.D. can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications. The fax phone numbers for the customer service center is 703-872-9305.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

CJN  
September 18, 2002

*Gary d. Kunz*  
**GARY KUNZ**  
**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**